ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
TANF Tribal Plan	18	1	60	1,080

Estimated Total Annual Burden Hours: 1,080.

Additional Information: ACF is requesting that OMB grant a 180 day approval for this information collection under procedures for emergency processing by April 9, 1997. A copy of this information collection, with applicable supporting documentation, may be obtained by calling the Administration for Children and Families, Reports Clearance Officer, Larry Guerrero at (202) 401–6465.

Comments and questions about the information collection described above should be directed to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for ACF, Office of Management and Budget, Paperwork Reduction Project, 725 17th Street NW., Washington, DC 20503, (202) 395–7316.

Dated: April 8, 1997.

Larry Guerrero,

Reports Clearance Officer.

[FR Doc. 97–9535 Filed 4–11–97; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of the Committee: Device Good Manufacturing Practice Advisory Committee.

General Function of the Commitee: To provide advice and recommendations to the agency on FDA regulatory issues.

Date and Time: The meeting will be held on April 29, 1997, 8:30 a.m. to 5 p.m.

Location: Parklawn Bldg., Conference room D, 5600 Fishers Lane, Rockville, MD.

Contact Person: Sharon M. Kalokerinos, Center for Devices and Radiological Health (HFZ–331), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 301–594–4613, ext. 139, or FDA Advisory Committee Information line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12398. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will consider a proposed plan developed by the Center for Devices and Radiological Health (CDRH) to introduce a risk-based planning model for determining where headquarters and field enforcement resources should be focused. The model to be presented calls for greater emphasis on those products that present the greatest risk to public health, based on such factors as device classification (Class III and Class II/Tier 3 products), current knowledge of product performance, and information from the recall and medical device reporting (MDR) adverse event data bases. Those products that present minimal risk (Class I and some Class II) would receive less oversight. Areas being considered for increased coverage include premarket approval inspections (Class III products), inspections deemed necessary to address a risk to public health (for cause), followup to violative inspections, and inspections of devices identified by the risk-based model.

There are two aspects to this planning model: (1) The identification of top priority devices which would receive a more indepth evaluation in terms of causes associated with failures and malfunctions reported in the data bases; and (2) the utilization of risk criteria such as the classification and tiering of devices to determine the parameters of routine good manufacturing practice (GMP) surveillance, both the frequency and depth of inspectional coverage.

Data used to identify top priority devices would undergo a quality control evaluation to determine the basis for the large numbers of reports in the data systems. For example, the recall information would be evaluated to assure that inclusion on the list is based on substantive causes of the recall and not on isolated events. Likewise, MDR information would be evaluated for public health risk versus reporting artifacts. Scientific implications of failures/malfunctions would form the basis of the investigational assignments issued, and CDRH staff would analyze the data collected for commonalities and trends. Resolution of issues noted may vary depending upon the nature of the problems. Options include technical and scientific discussions, training initiatives by FDA or industry, or compliance followup activities.

The plan proposes a tiered approach to conducting routine GMP surveillance inspections. Devices carrying a higher risk for the patient such as Class III and Class II/Tier 3 would be inspected more frequently. These higher risk devices will also receive comprehensive inspectional coverage and limited inspections will be conducted for the lower classifications and tiers.

Procedure: The meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by April 22, 1997. Those desiring to make formal presentations should notify the contact person, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the aproximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committe Act (5 U.S.C. app. 2).

A limited number of overnight accommodations have been reserved at the DoubleTree Hotel. Attendees requiring overnight accommodations may contact the hotel at 301–468–1100 and reference the FDA Device Good Manufacturing Practice Advisory Committee meeting block. Reservations will be confirmed at the group rate based on availability. Attendees with a disability requiring special accommodations should contact Christie Wyatt, KRA Corp., 301–495–1591, ext. 224. The availability of appropriate accommodations cannot be assured unless prior written notification is received.

Dated: April 8, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97–9528 Filed 4–11–97; 8:45 am]

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